



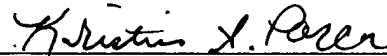
PATENT  
Attorney Docket No. EXT-048

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT(S): Shuber  
SERIAL NO.: 09/755,004 GROUP NO.: 1637  
FILING DATE: January 5, 2001 EXAMINER: S. Chunduru  
TITLE: Methods for Detecting, Grading or Monitoring an H. pylori Infection

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 29<sup>th</sup> day of September, 2003.

  
\_\_\_\_\_  
Kristin A. Porcu

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith is/are:

1. Transmittal Form (1 page);
2. Fee Transmittal Form (1 page);
3. Supplemental Information Disclosure Statement (2 pages);
4. Supplemental Form PTO-1449 (1 page);
5. Copies of cited references (B12-B14 and C62-C67);
6. a check in the amount of \$180.00; and
7. Return Receipt Postcard.

# **FEE TRANSMITTAL** **FY 2003**

OCT 01 2003

Complete if Known

Application Serial Number	09/755,004
Filing Date	January 5, 2001
First Named Inventor	Shuber
Group Art Unit	1637
Examiner Name	S. Chunduru
Attorney Docket No.	EXT-048

## **METHOD OF PAYMENT**

- ☒ Payment Enclosed:  
☒ Check ☐ Money Order ☐ Other
- ☒ The Commissioner is hereby authorized to credit or charge any fee indicated below for this submission to Deposit Account No. 20-0531.  
☐ Required Fees (copy of this sheet enclosed).  
☒ Additional fee required under 37 CFR 1.16 and 1.17.  
☒ Overpayment Credit.
- ☐ Applicant claims small entity status.

## **FEE CALCULATION**

### **1. FILING FEE**

#### **Large Entity**

Fee (\$)	Fee Description	Fee Paid
750	Utility filing fee	
330	Design filing fee	
160	Provisional filing fee	

Number Filed	Number Extra	Rate	Amount
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Total Claims - 20 = x \$ 18.00 =

Independent Claims - 3 = x \$ 84.00 =

☐ Multiple Dependent Claim(s), if any \$280.00 =

TOTAL:  
SMALL ENTITY DISCOUNT:  
SUBTOTAL (1) (\$ ) 0.00

### **2. AMENDMENT CLAIM FEES**

Claims Remaining After Amend.	Highest No. Previously Paid For	Present Extra	Rate	Fee Paid
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Total - = x \$ 18.00 =

Indep. - 9 = x \$ 84.00 =

☐ First Presentation of Multiple Dep. Claim + \$280.00 =

TOTAL: (\$)  
SMALL ENTITY DISCOUNT: (\$)  
SUBTOTAL (2) (\$ ) 0.00

## **FEE CALCULATION (continued)**

### **3. ADDITIONAL FEES**

Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid
130	65	Surcharge - late filing fee or oath	
50	25	Surcharge - late provisional filing fee or cover sheet	
130	130	Non-English specification	
2,520	2,520	Request for ex parte reexamination	
110	55	Extension for reply within first month	
410	205	Extension for reply within second month	
930	465	Extension for reply within third month	
1450	725	Extension for reply within fourth month	
1970	985	Extension for reply within fifth month	
320	160	Notice of Appeal	
320	160	Filing a brief in support of an appeal	
280	140	Request for oral hearing	
130	130	Petitions to the Commissioner	
180	180	Submission of Information Disclosure Statement	180.00
750	375	Filing a submission after final rejection (37 CFR 1.129(a))	
750	375	For each additional invention to be examined (37 CFR 1.129(b))	
100	100	Certificate of Correction for applicant's error	
110	55	Submission of Terminal Disclaimer	
Other fee (Specify)			
Other fee (Specify)			

SUBTOTAL (3) (\$ ) 180.00

SUBTOTAL (1) 0.00

SUBTOTAL (2) 0.00

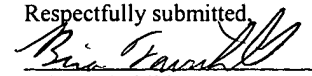
SUBTOTAL (3) 180.00

TOTAL (\$ ) 180.00

## **CORRESPONDENCE ADDRESS**

Direct all correspondence to:  
Patent Administrator  
Testa, Hurwitz & Thibault, LLP  
High Street Tower-125 High Street  
Boston, MA 02110  
Tel. No.: (617) 248-7000  
Fax No.: (617) 248-7100

## **SIGNATURE BLOCK**

Respectfully submitted,  
  
Date: September 29, 2003  
Reg. No.: 48,645  
Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7100  
Brian Fairchild  
Agent for the Applicants  
Testa, Hurwitz & Thibault, LLP  
High Street Tower-125 High Street  
Boston, MA 02110

OCT 01 2003

# TRANSMITTAL FORM

Application Serial Number	09/755,004
Filing Date	January 5, 2001
First Named Inventor	Shuber
Group Art Unit	1637
Examiner Name	S. Chunduru
Attorney Docket No.	EXT-048
Patent No.	Not applicable
Issue Date	Not applicable

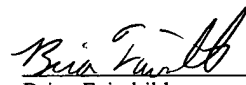
## ENCLOSURES (check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form  <input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]  <input type="checkbox"/> Petition for Extension of Time  <input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application  <input type="checkbox"/> Formal Drawing(s)  <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal  <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application  <input type="checkbox"/> Small Entity Statement  <input type="checkbox"/> CD(s) for large table or computer program  <input type="checkbox"/> Amendment After Allowance  <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences  <input type="checkbox"/> Appeal Brief (in triplicate)  <input type="checkbox"/> Status Inquiry  <input checked="" type="checkbox"/> Return Receipt Postcard <input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8  <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8  <input type="checkbox"/> Additional Enclosure(s) (please identify below)
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 Testa, Hurwitz & Thibault, LLP  
 High Street Tower  
 125 High Street  
 Boston, MA 02110  
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 Date: September 29, 2003  
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 125 High Street  
 Boston, MA 02110



PATENT  
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SERIAL NO.: 09/755,004 GROUP NO.: 1637  
FILING DATE: January 5, 2001 EXAMINER: S. Chunduru  
TITLE: Methods for Detecting, Grading or Monitoring an H. pylori Infection

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

**REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

10/06/2003 SDENB081 00000010 09755004

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180.00 00

- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

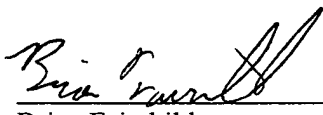
It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

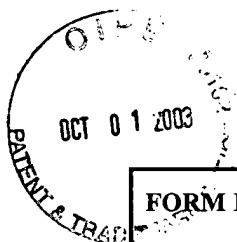
Applicants note that C67 is the international search report for reference B14, a PCT counterpart of the present U.S. application.

Respectfully submitted,

Date: September 29, 2003  
Reg. No. 48,645

Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7970

  
\_\_\_\_\_  
Brian Fairchild  
Agent for Applicant(s)  
Testa, Hurwitz, & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110



SHEET 1 OF 1

<b>FORM PTO - 1449</b>					<b>ATTORNEY DOCKET NO.: EXT-048</b>				
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>					<b>APPLICANT(S): Shuber</b>				
					<b>SERIAL NO.: 09/755,004</b>				
					<b>FILING DATE: January 5, 2001</b>		<b>GROUP: 1637</b>		
<b>FOREIGN PATENT DOCUMENTS</b>									
<b>EXAM. INIT.</b>		<b>DOCUMENT NUMBER</b>	<b>DATE</b>	<b>COUNTRY CODE</b>	<b>CLASS</b>	<b>SUB CLASS</b>	<b>FILING DATE</b>	<b>ABSTRACT ONLY</b>	<b>ENGLISH LANG (Y/N)</b>
	B12	WO 00/50640	31.08.00	PCT	C12Q	1/68	24.01.00	N	Y
	B13	WO 01/18252	15.03.01	PCT	C12Q	1/68	08.09.00	N	Y
	B14	WO 02/059379 A2	01.08.02	PCT	C12Q	1/68	04.01.02	N	Y
<b>OTHER ART, JOURNAL ARTICLES, ETC.</b>									
<b>EXAM. INIT.</b>	<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>								
	C62	Giacona <i>et al.</i> , "Cell-Free DNA in Human Blood Plasma: Length Measurements in Patients with Pancreatic Cancer and Healthy Controls," <u>Pancreas</u> , 17(1): 89-97 (1998).							
	C63	Husson <i>et al.</i> , "Importance in Diagnosis of Gastritis of Detection by PCR of the <i>cagA</i> Gene <i>Helicobacter pylori</i> Strains Isolated from Children," <u>J. Clin. Microbiol.</u> , 33(12): 3300-3303 (Dec. 1995).							
	C64	Lu <i>et al.</i> , "Comparison of Five PCR Methods for Detection of <i>Helicobacter pylori</i> DNA in Gastric Tissues," <u>J. Clin. Microbiol.</u> , 37(3): 772-774 (Mar. 1999).							
	C65	Riggio <i>et al.</i> , "Detection of <i>Helicobacter pylori</i> DNA in recurrent aphthous stomatitis tissue by PCR," <u>J. Oral Pathol. Med.</u> , 29: 507-513 (2000).							
	C66	Wagner <i>et al.</i> , "Regulation of Gastric Epithelial Cell Growth by <i>Helicobacter pylori</i> : Evidence for a Major Role of Apoptosis," <u>Gastroenterology</u> , 113: 1836-1847 (Dec. 1997).							
	C67	Patent Cooperation Treaty, International Search Report, International Application No. PCT/US 02/00267, mailed on July 2, 2003, 5 pages.							
<b>EXAMINER</b>					<b>DATE CONSIDERED</b>				

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